

# Exhibit B



**U.S. Department of Justice**  
**Criminal Division**  
*Fraud Section*

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January 27, 2025

**VIA ELECTRONIC MAIL**

**Scottie Allen**

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**Re: United States v. Gray., 9:22-CR-80022**  
**Expert Disclosure – Shauna Schwarm (Hull)**

Dear Counsel:

The United States of America provides this supplemental notice and a written summary of the expected testimony of Shauna Schwarm (Hull) (referred to throughout this document as Ms. Schwarm) described below, whom the government currently intends to call at trial during its case-in-chief (“Notice”),<sup>1</sup> in compliance with its obligations under Federal Rule of Criminal Procedure 16(a)(1)(G), as well as Federal Rules of Evidence (“FRE”) 702, 703, and 705. The government may choose not to attempt to elicit the testimony outlined in this Notice but provides this information in order to comply with the applicable rules.

Ms. Schwarm may also testify as a fact witness in this case regarding matters of which she has personal knowledge under FRE 602 and about which she may opine under FRE 701. This Notice does not serve either to summarize such testimony or to limit the subject areas about which she may testify.

The government acknowledges its continuing duty to disclose evidence or material obtained before or during trial pursuant to Federal Rule of Criminal Procedure 16(c). Should unexpected events arise between now and trial which might require additional or different expert testimony, the government will promptly seek the Court’s permission to offer the testimony of additional or alternative expert witnesses.

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<sup>1</sup> On November 1, 2024, we previously provided notice of Ms. Schwarm’s anticipated testimony. We are issuing this letter as a supplement to that original notice, to comply with Federal Rule of Criminal Procedure 16(a)(1)(G), and to include additional detail related to Ms. Schwarm’s anticipated testimony. As before, the government is providing this disclosure out of an abundance of caution even though the Government believes that Ms. Schwarm’s anticipated testimony described herein is factual such that it should be received as lay opinion pursuant to FRE 701.

The United States intends to call Shauna Schwarm, or another witness, to explain how Medicare works, Medicare's coverage for laboratory testing (including the cardio genetic testing conducted in this case), Medicare's coverage for telemedicine, the fact that Medicare does not cover claims based on kickbacks or bribes, the representations that providers, including owners of laboratories, must make to enroll with Medicare, and the claims submitted by the Defendant's laboratories to Medicare. Ms. Schwarm is not being specifically compensated for her testimony in this case; instead, trial testimony is part of her ordinary duties as set forth below.

The government has previously provided Ms. Schwarm's CV and transcripts of Ms. Schwarm's prior testimony, to the extent they are in the government's possession, as well as information on her background and qualifications. In sum, Ms. Schwarm has worked for several Medicare contractors primarily in fraud investigations. She is currently employed by Qlarant Quality Solutions ("Qlarant") and supports the Southwest Unified Program Integrity Contractor ("UPIC"). In her current role, Ms. Schwarm is responsible for support and education for federal law enforcement agencies, training and development of staff, outreach activities relating to fraud and abuse, and coordinating and sharing information with the Centers for Medicare and Medicaid Services ("CMS"), other contractors, and law enforcement agencies. Ms. Schwarm has a decade of experience working with Medicare contractors. In addition, she has experience analyzing claims for payment to Medicare. Over her years in this industry, Ms. Schwarm has become familiar with Medicare's coverage for laboratory services and has overseen fraud investigations for Medicare contractors. She is also familiar with analyzing voluminous claims data. She has testified about Medicare and Medicare coverage in approximately nine federal criminal trials throughout Louisiana and Texas.

In the last four years, Ms. Schwarm has testified in the following cases:

- November 2020, Beaumont, TX, No. 1:20-CR-33
- March 2022, Houston, TX, No. 4:17-cr-00197
- April 2022, Sherman, TX, No. 4:20-cr-358 ALM
- April 2022, Houston, TX, No. 4:19-cr-00633
- October 2022, Houston, TX, No. 4:20-cr-00619
- March 2023, Lafayette, LA, No. 6:21-cr-00312
- October 2023, New Orleans, LA, No. 2:21-cr-00098
- February 2024, Dallas, TX, No. 3:22-cr-00259-S
- February 2024, McAllen, TX, No. 7:22-cr-01311

Ms. Schwarm's opinions will be based on her knowledge, training, skill, and experience working with the Medicare program, including its rules and regulations, as well as her review and analysis of documents and claims data, which have been provided as discovery to the Defendant in this case.

The government anticipates that Ms. Schwarm's testimony may cover the following topics and include the following opinions, in addition to the topics and opinions disclosed in the November 1, 2024 letter:

## **1. Background on Medicare**

- Ms. Schwarm will testify that Medicare is a federally funded program that provides below-cost health care benefits to people aged 65 years or older, the blind, and the disabled. The Centers for Medicare & Medicaid Services (“CMS”), a unit of the Department of Health and Human Services (“HHS”) is responsible for the administration of Medicare. Ms. Schwarm will explain that individuals who receive benefits under Medicare are referred to as Medicare “beneficiaries.” Beneficiaries are eligible to receive a variety of services, including hospital and physician services (“Part B”). Part B covers outpatient physician services, such as office visits, minor surgical procedures, and laboratory services, when certain criteria are met.
- Ms. Schwarm will explain what a claim for payment from Medicare is, and what must be included to submit a claim for payment from Medicare, including the following: (1) the claim must pertain to a patient who was properly enrolled as a Medicare beneficiary; (2) the healthcare provider who furnished the services to the patient must be licensed in the state in which they practice and be properly enrolled with Medicare; (3) the services claimed must have been actually provided as reported on the claim; (4) the services claimed must be medically necessary and eligible for reimbursement under any applicable rules, regulations, or policies; and (5) the claim must be properly reported and properly documented with a supporting medical record.
- Ms. Schwarm will testify to the claims adjudication process, including the time in which Medicare processes claims and the extent to which claims are, or are not, reviewed by Medicare. She will testify that it is a physical impossibility for every claim to be reviewed before it is paid by Medicare. Instead, Medicare relies on the provider’s representation that claims are true and accurate.

## **2. Medicare Enrollment and Form 855**

- Ms. Schwarm will explain that “providers” include clinical laboratories, physicians, and other health care providers who provide services to beneficiaries. In order to bill Medicare, a provider must first obtain an NPI, then submit an enrollment application to Medicare. The enrollment application contains certification statements that the provider must agree to before enrolling with Medicare. Specifically, the certification statement sets forth, in part, that the provider agrees to abide by the Medicare laws, regulations, and program instructions, including the Federal Anti-Kickback Statute, and will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare.
- Ms. Schwarm will explain the representations that providers make regarding their ownership and management structure.
- Ms. Schwarm will explain that Medicare providers receive a “provider number,” which they use to file claims with, or “bill” Medicare to obtain reimbursement for services rendered to beneficiaries. When submitting claims to Medicare for reimbursement, providers certify that:

(1) the contents of the forms are true, correct, and complete; (2) the forms are prepared in compliance with the laws and regulations governing Medicare; and (3) the services purportedly provided, as set forth in the claims, are medically necessary.

- Ms. Schwarm will discuss the Form 855s as well as other documentation submitted by the various clinical laboratories referenced in the Indictment, including representations contained within the forms as to providers' ownership, management, location(s), and promises made in those forms to comply with applicable rules and regulations and to not submit false claims.

### **3. Genetic Testing**

- Ms. Schwarm will testify that this case implicates claims submitted to Medicare for laboratory services, namely, genetic testing, including cardiovascular genetic ("cardio") tests.
- Ms. Schwarm will explain Medicare's reimbursement policies with respect to such testing, and she will testify that Medicare reimburses for the test at rates varying from approximately a few hundred dollars to several thousand dollars for a panel of tests. Ms. Schwarm will explain that Medicare does not pay for every potential medical service, and instead, many services are expressly excluded from coverage.
- Ms. Schwarm will testify that as a condition of Medicare payment, a physician or other Medicare provider must certify that the services performed were medically necessary as required by Title 42, United States Code, Section 1395n(a)(2)(B).
- Ms. Schwarm will testify that Medicare generally does not pay for "screening" tests, unless specifically covered by statute, which the genetic tests billed in this case were not. Rather, lab testing must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A); see also 42 C.F.R. § 411.15(a)(1); 42 C.F.R. § 410.10(e).
- Ms. Schwarm will explain that laboratory tests must also be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results of the test in the management of the beneficiary's specific medical problem. Ms. Schwarm will testify that Medicare does not cover genetic tests that are not ordered by the beneficiary's treating physician because CMS has determined that tests not ordered by the physician treating the beneficiary are not reasonable and necessary. *See* 42 C.F.R. § 410.32(a).
- Certain screening tests are exempted from the general exclusion from coverage, such as routine mammography or colonoscopy exams (among other routine screening exams). Ms. Schwarm will contrast routine screening tests expressly covered under statute from genetic testing billed in this case, which is not generally eligible for reimbursement by Medicare on the basis that such testing is not reasonable and not necessary.

- Ms. Schwarm will discuss and explain that Medicare publishes guidance regarding what services it does and does not cover in a variety of publications, including National Coverage Determinations (“NCDs”) and Local Coverage Determinations (“LCDs”). Ms. Schwarm will discuss the applicable NCDs and LCDs published in the relevant Medicare Administrative Contractor (“MAC”) geographic jurisdictions, during the charged conspiracy.
- Even if a genetic test satisfies the applicable statutory and regulatory requirements above, the test must also satisfy applicable LCD coverage limitations. Ms. Schwarm will discuss the LCDs issued by the MACs for the relevant Medicare jurisdictions and their respective limitations of coverage of specific genetic tests as well as billing trends associated with the publication and implementation of certain LCDs and NCDs.
- Ms. Schwarm will also explain Medicare’s rules related to providers’ record-keeping requirements and requirements related to documenting medical necessity in the patient record. Specifically, Ms. Schwarm will explain that Medicare requires ordering/referring physicians to document medical necessity and other coverage for genetic testing. Medicare regulations require health care providers enrolled with Medicare to maintain complete and accurate patient medical records reflecting the medical assessment and diagnoses of their patients, as well as records documenting actual treatment of the patients to whom services were provided and for whom claims for payment were submitted by the physician.
- Ms. Schwarm will explain that Medicare would not reimburse a provider for claims if Medicare knew that the claims were based on kickbacks and/or bribes.

#### **4. Billing in This Case**

- Ms. Schwarm will explain the Medicare rules and regulations regarding claims and reimbursement for genetic testing.
- Ms. Schwarm may summarize claims data and billing patterns in this case.

#### **5. Why Kickbacks Are Illegal**

- Ms. Schwarm will apply her knowledge of Medicare rules and regulations to explain that kickbacks are illegal because they incentivize providers to bill for medically unnecessary services.

#### **6. Information Relied Upon by Ms. Schwarm**

- To date, in addition to the materials described in the November 1, 2024 letter, Ms. Schwarm has been provided the following records by the prosecution team to assist in her review, which have been provided to the defense in this case, in addition to publicly available statutes, regulations, and guidance, some of which is referenced herein: Government Exhibits 1-9 (the

Medicare provider enrollment documents, claims data, and Local Coverage Determinations and articles).

Warm regards,

/s/ Adam Tisdall

Adam Tisdall

Trial Attorney

U.S. Department of Justice

Criminal Division, Fraud Section

I, Shauna Schwarm (Hull), have reviewed this disclosure and approve of its contents.

*Shauna Schwarm*

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Shauna Schwarm (Hull)

*1-27-2025*

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Date